# Food and Drug Administration, HHS

- (2) Sponsor. See No. 000009 i §510.600(c) of this chapter.
- (3) Related tolerances. See §556.460 of this chapter.
- (4) Conditions of use—(i) Amount. Infuse 10 milliliters (equivalent to 150 milligrams of novobiocin) in each quarter after milking. Repeat treatment once after 24 hours.
- (ii) *Indications for use.* Use in lactating cows for treatment of mastitis caused by susceptible strains of *Staphylococcus aureus*.
- (iii) Limitations. Do not milk for at least 6 hours after treatment; afterwards, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after latest treatment must not be used for food. Do not slaughter treated animals for food for 15 days following latest treatment. If redness, swelling, or abnormal milk persists or increases after treatment, discontinue use and consult a veterinarian. For udder instillation in lactating cattle only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 10554, Mar. 14, 1978]

# § 526.1696 Penicillin intramammary dosage forms.

## §526.1696a Penicillin G procaine.

- (a) Specifications. Each 10-milliliter single-dose syringe contains penicillin G procaine equivalent to 100,000 units of penicillin G.
- (b) Related tolerances. See §556.510 of this chapter.
- (c) *Sponsors*. See Nos. 010515 and 061623 in §510.600(c) of this chapter.
- (d) Conditions of use in lactating cows—(1) Amount. Infuse one 10-milliliter dose into each infected quarter. Treatment may be repeated at 12-hour intervals for not more than three doses, as indicated by clinical response.
- (2) Indications for use. For the treatment of mastitis caused by Streptococcus agalactiae, S. dysgalactiae, and S. uberus in lactating cows.
- (3) Limitations. Milk that has been taken from animals during treatment and for 60 hours after the latest treatment must not be used for food. Animals must not be slaughtered for food during treatment or within 3 days after the latest treatment.

- (e) Conditions of use in dry cows—(1) Amount. Infuse one 10-milliliter dose into each infected quarter at time of drying-off.
- (2) Indications of use. For the treatment of mastitis caused by Streptococcus agalactiae in dry cows.
- (3) Limitations. Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable quality of the milk. Animals must not be slaughtered for food within 14 days postinfusion.

[73 FR 18442, Apr. 4, 2008, as amended at 74 FR 18990, Apr. 27, 2009]

#### § 526.1696b Penicillin G procaine-dihydrostreptomycin in soybean oil for intramammary infusion (dry cows).

- (a) Specifications. Each 10 milliliters of suspension contains penicillin G procaine equivalent to 200,000 units of penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams of dihydrostreptomycin.
- (b) *Sponsor*. See No. 000010 in §510.600(c) of this chapter.
- (c) Related tolerances. See §§ 556.200 and 556.510 of this chapter.
- (d) Conditions of use. Dairy cows—(1) Amount. One syringe into each quarter at the last milking prior to drying off.
- (2) Indications for use. Intramammary treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by Staphylococcus aureus and Streptococcus agalactiae.
- (3) Limitations. Not to be used within 6 weeks of calving. For use in dry cows only. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment nor within 24 hours after calving.

[57 FR 37336, Aug. 18, 1992]

### § 526.1696c Penicillin G procaine-dihydrostreptomycin sulfate for intramammary infusion (dry cows).

- (a) Specifications. Each 10 milliliters of suspension contains penicillin G procaine equivalent to 1 million units of penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram of dihydrostreptomycin.
- (b) Sponsor. See No. 033392 in §510.600(c) of this chapter.

## § 526.1696d

- (c) Related tolerances. See §§ 556.200 and 556.510 of this chapter.
- (d) Conditions of use. Dairy cows—(1) Amount. One syringe per quarter at the last milking prior to drying off.
- (2) Indications for use. Intramammary use to reduce the frequency of existing infection and to prevent new infections with Staphylococcus aureus in dry cows.
- (3) Limitations. Not to be used within 6 weeks of freshening. Not for use in lactating cows. Milk taken from animals within 96 hours (8 milkings) after calving must not be used for feed. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion nor within 96 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

#### § 526.1696d Penicillin G procainenovobiocin for intramammary infusion.

- (a) Specifications. For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.
- (b) *Sponsor*. See No. 000009 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Lactating cows—(i) Amount. 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.
- (ii) Indications for use. Treating lactating cows for mastitis caused by susceptible strains of Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, and Streptococcus uberis.
- (iii) Limitations. For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

- (2) Dry cows—(i) Amount. 10 milliliters in each quarter at time of drying off.
- (ii) *Indications for use*. Treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae*.
- (iii) Limitations. For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

#### § 526.1810 Pirlimycin.

- (a) Specifications. Each 10-milliliter syringe contains 50 milligrams (mg) pirlimycin (as pirlimycin hydrochloride).
- (b) Sponsor. See No. 000009 in  $\S510.600(c)$  of this chapter.
- (c) Related tolerances. See §556.515 of this chapter.
- (d) Conditions of use in cattle—(1) Amount. Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.
- (2) Indications for use. For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with Staphylococcus species such as Staphylococcus aureus and Streptococcus species such as Streptococcus agalactiae, Streptococcus dysgalactiae, and Streptococcus uberis.
- (3) Limitations. Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- $[58\ FR\ 58486,\ Nov.\ 2,\ 1993,\ as\ amended\ at\ 65\ FR\ 61091,\ Oct.\ 16,\ 2000;\ 73\ FR\ 811,\ Jan.\ 4,\ 2008]$